

CLAIMS

1. An apparatus implantable in a heart ventricle comprising:
a frame configured to engage an inner circumferential periphery of a ventricle and to expand and contract between an expanded state corresponding to a desired end diastolic
5 diameter of a ventricle and a contracted state corresponding to a desired end systolic diameter of the ventricle; and
assisting means operatively associated with the frame for mechanically assisting movement of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole.
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2. The apparatus of claim 1 wherein the assisting means assists movement of the ventricle toward both end systolic diameter during systole and end diastolic diameter during diastole.
- 15 3. The apparatus of claim 1 wherein the assisting means assists movement of the ventricle toward only end diastolic diameter during diastole.
4. The apparatus of claim 1 wherein the assisting means is integrally formed with the frame.
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5. The apparatus of claim 1 wherein the frame comprises a bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and an end diastolic diameter.
- 25 6. The apparatus of 5 further comprising means operatively associated with the bistable element for limiting the expanded stable state.
7. The apparatus of claim 5 wherein the bistable element comprises a plurality of longitudinal bands each having a top and a bottom end, the top ends of the longitudinal bands
30 being joined by a top circumferential band extending therebetween and the bottom ends of the longitudinal bands being joined by a bottom circumferential band extending therebetween.

8. The apparatus of claim 7 wherein in the expanded state the longitudinal bands have a concave cross section relative to an inner surface of the bands and in the contracted state the longitudinal bands have a convex cross section relative to the inner surface of the bands.

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9. The apparatus of claim 7 wherein the longitudinal bands are made of memory metal.

10. The apparatus of claim 7 wherein the top circumferential band joining the top ends of the longitudinal bands is split across its circumference, the top band being self-biased to define a space between ends adjacent to the split.

11. The apparatus of claim 9 further comprising means for connecting the ends adjacent to the split to define a substantially circular top band.

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12. The apparatus of claim 7 further comprising recesses along lengthwise edges of the longitudinal bands configured to promote flexing of the longitudinal bands between the contracted and expanded bistable states.

20 13. The apparatus of claim 7 further comprising the bottom circumferential band being configured to perform as a spring.

25 14. The apparatus of claim 7 further comprising a mitral annuloplasty ring extending axially from a top of the bistable element, the bistable element and the mitral annuloplasty ring being configured so that with the bistable element attached to myocardium defining the inner circumferential periphery of a left ventricle, the mitral annuloplasty ring is below but proximate the mitral annulus.

30 15. The apparatus of claim 14 wherein the top and bottom circumferential bands are split across their circumferences to define C-shaped bands.

16. The apparatus of claim 15 wherein the mitral annuloplasty ring is split across its circumference to define a C-shape, the split of the top and bottom circumferential bands and the mitral annuloplasty ring being axially aligned.

5 17. The apparatus of claim 1 wherein the assisting means comprises the frame being configured to self-bias between the expanded and contracted bistable states when circumferentially deflected beyond a select point toward the other of the bistable states.

10 18. The apparatus of claim 1 having a generally elliptical profile in the expanded state and a generally hour-glass profile in the contracted state generally conforming to an ideal end diastolic and end systolic ventricle shape, respectively.

15 19. The apparatus of claim 1 further comprising a biocompatible sheath around the frame and the assisting means.

20 20. The apparatus of claim 1 wherein the frame and the assisting means comprise:
a resilient band;
a spring element operatively associated axially with the resilient band; and
means for joining the ends of the resilient band into a circle;
20 the resilient band being configured, with the ends joined, to engage an inner circumferential periphery of a ventricle, with the spring element in a relaxed state during one of an end diastolic or end systolic state of the ventricle.

25 21. The apparatus of claim 20 further comprising means limiting the diameter of the resilient band during end diastole.

22. The apparatus of claim 20 further comprising the spring element being integrally formed of the resilient band.

30 23. The apparatus of claim 22, wherein the spring element comprises concertina deformations in the resilient band.

24. The apparatus of claim 20 further comprising at least two spring elements, a plane section separating each spring element.

25. The apparatus of claim 22 further comprising a biocompatible sheath receiving
5 the resilient band, the biocompatible sheath comprising a plurality of lengthwise tubes and a ligature being fed through the lengthwise tubes of the sheath.

26. The apparatus of claim 20 further comprising a mitral annuloplasty ring
extending axially of the resilient band with the resilient band formed into a circle.
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27. The apparatus of claim 26 further comprising at least two legs joining the mitral annuloplasty ring to the resilient band.

28. The apparatus of claim 26 wherein the mitral annuloplasty ring is substantially
15 C-shaped.

29. A method of treating cardiac disease comprising:
surgically accessing a ventricle;
inserting within the ventricle an apparatus configured to mechanically assist movement
20 of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole; and
attaching the device to a portion of myocardium defining an inner circumferential periphery of the ventricle.

25 30. The method of claim 29 wherein the apparatus comprises a bistable apparatus configured to engage the inner circumferential periphery of the ventricle, the bistable element having a contracted stable state and an expanded stable state corresponding to an end systolic diameter and an end diastolic diameter, respectively.

30 31. The method of claim 30, the bistable apparatus further comprising a plurality of longitudinal bands each having a top and a bottom end, the top ends of the longitudinal bands being joined by a top circumferential band extending therebetween and the bottom ends of the longitudinal bands being joined by a bottom circumferential band extending therebetween, the

top circumferential band joining the top ends of the longitudinal bands being split across its circumference, the top band being self-biased to define a space between ends adjacent to the split, the method further comprising:

- 5 during the inserting step, passing the chordae tendineae through the space between the ends adjacent to the split; and
attaching the adjacent ends together to form the top band into a circle.

32. The method of claim 31 further comprising:
surgically accessing a left ventricle;
10 attaching the longitudinal bands to the inner circumferential periphery of the ventricle;
attaching the top circumferential band to the myocardium proximate the mitral annulus;
and
attaching the bottom circumferential band to the myocardium proximate the ventricle apex.

- 15 33. The method of claim 30, the bistable apparatus further comprising a plurality of longitudinal bands each having a top and a bottom end, the top ends of the longitudinal bands being joined by a top circumferential band extending therebetween and the bottom ends of the longitudinal bands being joined by a bottom circumferential band and a mitral annuloplasty
20 ring extending axially from the top circumferential band, the bistable element and the mitral annuloplasty ring being configured so that with the bistable element attached to myocardium defining the inner circumferential periphery of a left ventricle, the mitral annuloplasty ring is below but proximate the mitral annulus, the method further comprising:

- 25 attaching the mitral annuloplasty ring to the myocardium subannularly proximate the mitral annulus.

34. The method of claim 29 wherein in the inserting step the apparatus comprises a resilient band comprising at least one spring element operatively associated axially with the resilient band to allow axial stretching and compression of the resilient band, the inserting step
30 further comprising placing the resilient band into contact with the inner circumferential periphery of the ventricle and forming the resilient band into a loop of a diameter about equal to an end diastolic diameter an inner circumferential periphery of the ventricle.

35. The method of claim 34 wherein the attaching step is performed by placing circumferentially spaced sutures in engagement with the resilient band loop and passing the sutures through the ventricle.

5 36. The method of claim 34 wherein the resilient band includes at least one circumferential ligature operatively associated with the resilient band, the circumferential ligature having opposing free ends, the method further comprising:
 forming the resilient band into a loop by tying the opposing free ends of the ligature together.

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 37. The method of claim 34 further comprising:
 in surgically accessing a left ventricle; and
 placing the resilient band into contact with the inner circumferential periphery of the left ventricle proximate the papillary muscles.

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 38. The method of claim 37 further comprising, receiving the chordae tendineae within the resilient band as the resilient band is placed into contact with the inner circumferential periphery of the left ventricle.

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 39. The method of claim 38 wherein the resilient band includes at least two plane sections separated by spring elements along its length, the method further comprising:
 following forming the resilient band into a loop, rotating the loop about its axis to align the plane sections adjacent to the papillary muscles.

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 40. The method of claim 29 further comprising, prior to the inserting step, performing a surgical ventricular reduction.

 41. The method of claim 40 further comprising: placing a portion of a trained latissimus dorsae muscle around the band within the heart.

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 42. The method of claim 40 further comprising: wrapping a portion of a trained latissimus dorsae muscle outside the ventricle about the inner circumferential periphery of the ventricle.

43. The method of claim 34 wherein the resilient band further comprises a mitral annuloplasty ring extending axially of the resilient band with the resilient band formed into a circle, the method further comprising:

5 attaching the mitral annuloplasty ring to the myocardium below but proximate the mitral annulus.

44. An apparatus implantable in a heart ventricle comprising:
a bistable element configured to engage an inner circumferential periphery of a
10 ventricle, the bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and diastolic diameter.

45. The apparatus of claim 44 further comprising means for attaching the bistable
element to myocardium defining the inner circumferential periphery of the ventricle.
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46. The apparatus of claim 44 further comprising means operatively associated
with the bistable element for limiting the expanded stable state of the bistable element.

47. The apparatus of claim 44 wherein the bistable element comprises a plurality of
20 longitudinal bands each having a top and a bottom end, the top ends of the longitudinal bands being joined by a top circumferential band extending therebetween and the bottom ends of the longitudinal bands being joined by a bottom circumferential band.

48. The apparatus of claim 47 wherein each circumferential band defines a closed
25 loop.

49. The apparatus of claim 47 wherein at least the top circumferential band is split
across the circumference to define a C-shaped band.

50. The apparatus or claim 47 wherein in the expanded state the longitudinal bands
30 have a concave cross section relative to an inner surface of the bands and in the contracted state the longitudinal bands have a convex cross section relative to the inner surface of the bands.

51. The apparatus of claim 47 wherein the longitudinal bands are made of memory metal.

5 52. The apparatus of claim 47 wherein the top circumferential band joining the top ends of the longitudinal bands is split across its circumference, the top band being self-biased to define a space between ends adjacent to the split.

10 53. The apparatus of claim 52 further comprising means for connecting the ends adjacent to the split to define a substantially circular top band.

54. The apparatus of claim 47 further comprising recesses along lengthwise edges of the longitudinal bands configured to promote flexing of the longitudinal bands between the contracted and expanded bistable states.

15 55. The apparatus of claim 47 further comprising the bottom circumferential band being configured to perform as a spring.

20 56. The apparatus of claim 47 further comprising a mitral annuloplasty ring extending axially from a top of the bistable element, the bistable element and the mitral annuloplasty ring being configured so that with the bistable element attached to myocardium defining the inner circumferential periphery of a left ventricle, the mitral annuloplasty ring is below but proximate the mitral annulus.

25 57. The apparatus of claim 56 wherein the top and bottom circumferential bands are split across their circumferences to define C-shaped bands.

30 58. The apparatus of claim 57 wherein the mitral annuloplasty ring is split across its circumference to define a C-shape, the split of the top and bottom circumferential bands and the mitral annuloplasty ring being axially aligned.

59. The apparatus of claim 44 wherein the bistable element is configured to self-bias between the expanded and contracted bistable states when circumferentially deflected beyond a select point toward the other of the bistable states.

5 60. The apparatus of claim 44 having a generally elliptical profile in the expanded state and a generally hour-glass profile in the contracted state generally conforming to an ideal ventricle shape during end diastole and end systole, respectively.

61. A method of augmenting systolic contraction and diastolic relaxation of a heart
10 ventricle comprising:

providing a bistable element configured to engage an inner circumferential periphery of a ventricle, the bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and end diastolic diameter, respectively;

15 surgically accessing the ventricle;
inserting the bistable element within the ventricle; and
attaching the bistable element to a portion of myocardium defining the inner circumferential periphery of the ventricle.

62. The method of claim 61 further comprising limiting the expanded stable state of
20 the bistable element.

63. The method of claim 61, the bistable apparatus further comprising a plurality of longitudinal bands each having a top and a bottom end, the top ends of the longitudinal bands being joined by a top circumferential band extending therebetween and the bottom ends of the
25 longitudinal bands being joined by a bottom circumferential band extending therebetween, the top circumferential band joining the top ends of the longitudinal bands being split across its circumference, the top band being self-biased to define a space between ends adjacent to the split, the method further comprising:

30 during the inserting step, passing the chordae tendineae through the space between the ends adjacent to the split; and
attaching the adjacent ends together to form the top band into a circle.

64. The method of claim 63 wherein the adjacent ends are attached using of a suture.

65. The method of claim 63 further comprising:
5 surgically accessing a left ventricle;
attaching the longitudinal bands to the inner circumferential periphery of the ventricle;
attaching the top circumferential band to the myocardium proximate the mitral annulus;
and
attaching the bottom circumferential band to the myocardium proximate the ventricle
10 apex.

66. The method of claim 63 further comprising extending cables between opposing longitudinal bands to limit the diameter of the expanded stable state.

67. The method of claim 61, the bistable apparatus further comprising a plurality of longitudinal bands each having a top and a bottom end, the top ends of the longitudinal bands being joined by a top circumferential band extending therebetween and the bottom ends of the longitudinal bands being joined by a bottom circumferential band and a mitral annuloplasty ring extending axially from the top circumferential band, the bistable element and the mitral annuloplasty ring being configured so that with the bistable element attached to myocardium defining the inner circumferential periphery of a left ventricle, the mitral annuloplasty ring is below but proximate the mitral annulus, the method further comprising:
attaching the mitral annuloplasty ring to the myocardium subannularly proximate the mitral annulus.

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68. An apparatus implantable in a heart ventricle comprising:
a resilient band;
a spring element operatively associated axially with the resilient band; and
means for joining the ends of the resilient band into a circle;
30 the resilient band being configured, with the ends joined, to engage an inner circumferential periphery of a ventricle, with the spring element in a relaxed state during diastole of the ventricle.

69. The apparatus of claim 68 further comprising a biocompatible sheath around the resilient band and spring element.

70. The apparatus of claim 68 further comprising means limiting the diameter of the resilient band during diastole.

71. The apparatus of claim 68 further comprising the spring element being integrally formed of the resilient band.

72. The apparatus of claim 71, wherein the spring element comprises concertina deformations in the resilient band.

73. The apparatus of claim 72 further comprising at least two spring elements, a plane section separating each spring element.

74. The apparatus of claim 69 wherein the biocompatible sheath comprises a plurality of lengthwise tubes, a ligature being fed through the lengthwise tubes of the sheath.

75. The apparatus of claim 68 further comprising a mitral annuloplasty ring extending axially of the resilient band with the resilient band formed into a circle.

76. The apparatus of claim 75 further comprising at least two legs joining the mitral annuloplasty ring to the resilient band.

77. The apparatus of claim 75 wherein the mitral annuloplasty ring is substantially C-shaped.

78. A method of treating cardiac disease comprising:
a) providing a resilient band having at least one spring element operatively associated axially with the resilient band to allow axial stretching and compression of the resilient band;
b) surgically accessing a ventricle of a heart;

c) placing the resilient band into contact with the inner circumferential periphery of the ventricle;

d) forming the resilient band into a loop of a diameter about equal to an end diastolic diameter of an inner circumferential periphery of the ventricle; and

5 e) attaching the resilient band loop to the myocardium defining the inner circumferential periphery of the ventricle.

79. The method of claim 78 wherein the attaching step is performed by placing circumferentially spaced sutures in engagement with the resilient band loop and passing the
10 sutures through the ventricle.

80. The method of claim 78 wherein the resilient band includes at least one circumferential ligature operatively associated with the resilient band, the circumferential ligature having opposing free ends, the method further comprising:
15 forming the resilient band into a loop by tying the opposing free ends of the ligature together.

81. The method of claim 78 further comprising:
in step b), surgically accessing a left ventricle; and
20 in step c), placing the resilient band into contact with the inner circumferential periphery of the left ventricle proximate the papillary muscles.

82. The method of claim 84 further comprising in step c), receiving the chordae tendineae within the resilient band as the resilient band is placed into contact with the inner
25 circumferential periphery of the left ventricle.

83. The method of claim 84 wherein the resilient band includes at least two plane sections separated by spring elements along its length, the method further comprising:
following forming the resilient band into a loop in step d), the loop is rotated about its
30 axis to align the plane sections adjacent to the papillary muscles.

84. The method of claim 78 further comprising:
b1) following step b), performing a surgical ventricular reduction.

85. The method of claim 84 further comprising:

d1) following step d), placing a portion of a trained latissimus dorsae muscle around the band within the heart.

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86. The method of claim 85 further comprising:

f) placing electrodes of a pacemaker into electric communication with the latissimus dorsae muscle.

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87. The method of claim 84 further comprising:

f) wrapping a portion of a trained latissimus dorsae muscle outside the ventricle about the inner circumferential periphery of the ventricle.

88. The method of claim 87 further comprising:

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g) placing electrodes of a pacemaker into electric communication with the latissimus dorsae muscle.

89. The method of claim 78 wherein the resilient band further comprises a mitral annuloplasty ring extending axially of the resilient band with the resilient band formed into a circle, the method further comprising:

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in step b), surgically accessing the left ventricle; and

f) attaching the mitral annuloplasty ring to the myocardium below but proximate the mitral annulus.